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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter Π of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

applicant's or agent's file reference '040007IP	FOR FURTHER ACTION	See Form PCT/IPEA/416			
nternational application No.	International filing date (day/n	ponth/year) Priority date (day/month/year) 15 August 2003			
*CT/AU2004/001081	13 August 2004	15 August 2005			
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Applicant MEDCARE SYSTEMS PTY L	TD et al				
l. This report is the international preliming Authority under Article 35 and transm		ned by this International Preliminary Examining Article 36.			
2 . This REPORT consists of a total of 3	sheets, including this cover shee	t.			
3. This report is also accompanied by AN	NEXES, comprising:				
a. X (sent to the applicant and to t	he International Bureau) a total c	f 11 sheets, as follows:			
sheets containing rectific Administrative Instruction sheets which supersede	cations authorized by this Author ons). earlier sheets, but which this Aut	ave been amended and are the basis for this report and/or ity (see Rule 70.16 and Section 607 of the nority considers contain an amendment that goes beyond indicated in item 4 of Box No. I and the Supplemental			
a sequence listing and/or tabl	e related thereto, in computer rea (see Section 802 of the Administ	and number of electronic carrier(s)) , containing dable form only, as indicated in the Supplemental Box rative Instructions).			
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<u></u>	Basis of the report				
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X Box No. V Reasoned state	Lack of unity of invention Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement				
	Certain documents cited				
Box No. VII Certain defects	Certain defects in the international application				
Box No. VIII Certain observ	rations on the international applic	ation			
Date of submission of the demand	Date o	f completion of the report			
11 March 2005		28 July 2005			
Name and mailing address of the IPEA/AU	Author	ized Officer			
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTI E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	RALIA A. A.				



International application No.

PCT/AU2004/001081

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	international search (under Rules 12.3 and 23.1 (b))						
		publication of	of the international application (under Rule 12.4)				
			preliminary examination (under Rules 55.2 and/or 55.3)	ļ			
fi	urnish	d to the receiving	ents of the international application, this report is based on (replacement sheets which have been g Office in response to an invitation under Article 14 are referred to in this report as "originall ed to this report):	<i>y</i>			
] th	international ap	plication as originally filed/furnished				
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		-	pages 6-16 as originally filed/furnished				
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		_	pages as originally filed/furnished pages* as amended (together with any statement) under Article 19				
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	•	the claim	s, Nos.				
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/AU2004/001081

lox No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

. Statement			
Novelty (N)	Claims 1-19	YES	
• (,	Claims	NO	
Inventive step (IS)	Claims 1-19	YES	
- , ,	Claims	NO	
Industrial applicability (IA)	Claims 1-19	YES	
	Claims	NO	

^{2.} Citations and explanations (Rule 70.7)

Claims 1-19 meet the criteria under PCT Articles 33(2)-33(4) with regard to novelty, inventive step and industrial applicability.

The notable difference between the invention as defined in claims 1-19 and what is disclosed in any of the cited references is that the processing unit of the monitoring apparatus not only determines the at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time but it also determines the at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia.

This feature provides the monitoring apparatus with an important adaptive threshold capability that is performed in situ within the processing unit itself and not a threshold that is determined by a clinician or other operator and inputted by specification.

This adaptive threshold capability provides two distinct advantages. Firstly, it caters for calibration or run in periods which do not require manual clinician or user intervention in relation to setting the threshold magnitudes, Secondly, it provides for adaptive cooperative changes to threshold magnitudes and mitigates against false alarms in the case of long term ambulatory performance changes.

The subject matter of claims 1-19 is therefore novel, involves an inventive step and possesses industrial applicability.

A MONITORING APPARATUS FOR AN AMBULATORY SUBJECT AND A METHOD FOR MONITORING THE SAME

FIELD OF THE INVENTION

5 The invention is in the field of monitoring methods and apparatus for ambulatory subjects.

PRIOR ART

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In accordance with the statistics in some countries the population is ageing and it is projected that by the year 2051 those aged 65 years and over will constitute approximately one quarter of the total population.

Falls are one of the greatest risks facing this group and in the over 65 age group, accidents are the fifth highest cause of death, and approximately two thirds of accidents are falls. Falls also account for more than half of all injury-related hospital admissions in this group.

Falls and collapse are associated with functional decline, leading to disability, dependence and nursing home placement, even in cases where the fall did not cause injury. Up to half of all older people who fall or collapse without suffering injuries are unable to get up without assistance.

In the case of the elderly or infirm persons living alone, an inability to rise can lead to serious consequences of extreme distress, muscle damage, pneumonia, pressure sores, dehydration, hypothermia and mortality. Many such people become afraid and so restrict their daily activities and exercise, which in turn leads to a further reduction in health and wellbeing.

Some personal alarm systems provide such venerable people with an emergency button however this technology is rendered ineffective if the person is unable to press the button due to unconsciousness, injury or immobility.

Furthermore the ageing population and the related increasing prevalence of chronic disease are placing a large burden on the hospital system. There is a need to provide alternatives to hospital care for these patients.

One of the most important considerations in independent living is functional status; that is, the ability of a person to carry out routine daily tasks in his or her normal (home) environment. There are many different measurements that provide indication of functional status. These include, but are not limited to, the time taken to rise from sitting, postural sway when standing, walking speed, and step rate variability. Traditionally, these parameters have been measured in a dedicated laboratory in an expensive, time-consuming procedure, or they have been measured subjectively in the clinic or home using clinician observation or patient recall.

It is therefore an object of the invention to overcome some of the problems of the prior art or at least to provide a useful alternative.

SUMMARY OF THE INVENTION

- One aspect of a preferred embodiment of the invention provides a monitoring apparatus for an ambulatory subject including:
 - a portable monitor mountable on the subject that includes an accelerometer that measures the instant acceleration of the subject in one or more determined directions;
 - a processing unit that:

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- a) determines at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time;
- b) determines at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia;
- determines if the subject's instant ambulatory performance indicia is below or above the at least one designated performance threshold;
- d) initiates at least one event if the determined instant ambulatory performance indicia is above or below the determined at least one designated performance threshold; and
- a communications unit that communicates an initiated event to a remote receiver.
- 20 Preferably the at least one designated performance threshold is determined by the processing unit from a plurality of previously determined instant ambulatory performance indicia.

Preferably the at least one event is initiated only if the determined instant ambulatory performance indicia is below or above the determined at least one designated performance threshold for a designated period of time.

Preferably the designated first period of time is determined from a plurality of previously determined instant ambulatory performance indicia.

30 Preferably the accelerometer simultaneously determines the acceleration of the subject in three orthogonal directions.

Preferably the portable monitor is configured to be mounted on an upright ambulatory such that one of the three orthogonal directions is in a vertical direction or within a designated angle of the vertical direction.

Preferably an Initiated event is communicated by the apparatus to the remote receiver by wireless communication.

In another embodiment it is also preferred:

- a first instant ambulatory performance indicia representative of movement activity in the subject is
 determined from the instant magnitude of the sum of the instant acceleration of the subject in one or
 more determined directions;
- a first acceleration threshold magnitude that is representative of a lack of normal expected subject movement is designated as a first designated performance threshold;
- a first event representative of 'an absence of a normal amount of movement in the subject indicative of a possible inability to rise due to a collapse or other adverse event' is initiated if the determined first instant ambulatory performance indicia is below the first designated acceleration threshold magnitude for a first designated period of time.

It is also further preferred:

- a second instant ambulatory performance indicia representative of the instant cranio—caudal angle of
 the subject relative to an upright disposition of the subject, is determined from at least one of the
 determined instant acceleration of the subject in one or more determined directions;
- an angle magnitude that is representative of a cranio-caudal angle of the subject relative to an upright subject where the disposition of the subject is deemed to be no longer upright is designated as a second designated performance threshold;
 - a second acceleration threshold magnitude representative of an abnormally high subject movement is designated as a third designated performance threshold; and
 - a second event representative of an abnormal acceleration of the subject followed by a laying down subject disposition indicative of a possible fall coupled with a subsequent absence of getting up from the laying down disposition indicative of a possible debilitating fall is initiated if:
 - a) the determined first instant ambulatory performance indicia is above the second designated acceleration threshold for a second designated period of time; and
 - within a third designated period of time of the end of the second designated period of time the determined second instant ambulatory performance indicia is greater than the designated angle threshold; and then
 - the determined first instant ambulatory performance indicla is below the first designated acceleration threshold magnitude for a first designated period of time.

Another aspect of the invention provides a method of monitoring an ambulatory subject including:

- a) mounting a portable monitor on the subject that includes an accelerometer to measure simultaneously the instant acceleration of the subject in at least three different directions at different instants in time;
- b) using a processing unit in communication with the portable monitor to determine a plurality of instant ambulatory performance Indicia based on the determined instant acceleration of the subject;

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- using the processing unit to determine at least one designated performance threshold corresponding to the each ambulatory performance indicia from at least one previously determined corresponding instant ambulatory performance indicia;
- d) using the processing unit to determine if the subject's instant ambulatory performance indicia is below or above the corresponding at least one designated performance threshold and initiating a corresponding event;
- e) using a communications unit to communicate an initiated event to a remote receiver.

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Preferably the at least one designated performance threshold is determined from a plurality of previously determined instant performance indicia, and the designated performance threshold responsively and cooperatively adapts to statistical changes in previously determined instant performance indicia over time.

Preferably the event is initiated only if the determined instant ambulatory performance indicia is below or above the determined at least one designated performance threshold for a designated period of time.

Another aspect of the invention provides a method of monitoring an ambulatory subject including:

- a) mounting a portable monitor on the subject that includes an accelerometer to measure the instant acceleration of the subject in one or more determined directions;
- using a processing unit in communication with the portable monitor to determine at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time;
- c) using the processing unit to determine at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia;
- d) using the processing unit to determine if the subject's instant ambulatory performance indicia is below or above the at least one designated performance threshold and initiating a corresponding event;
- using the processing unit to initiate at least one event if the determined instant ambulatory performance indicia is above or below the determined at least one designated performance threshold; and
- f) using a communications unit to communicate an initiated event to a remote receiver.

Preferably the at least one designated performance threshold is determined by the processing unit from a plurality of previously determined instant performance indicia.

35 Preferably the designated performance threshold responsively and cooperatively adapts to statistical changes in previously determined instant performance indicia over time.

Another aspect of the invention provides a monitoring apparatus for an ambulatory subject including:

- a portable monitor mountable on the subject that includes an accelerometer that simultaneously
 measures the instant acceleration of the subject in at least three different directions;
- a processing unit that:

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- a) is in communication with the portable monitor;
- determines the instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions;
- c) determines if the determined instant magnitude does not exceed a first designated
 acceleration threshold magnitude for a first designated period of time, where the first
 designated acceleration threshold magnitude is representative of a lack of normal expected
 subject movement;
- d) initiates an event representative of an absence of a normal amount of movement in the subject Indicative of a possible inability to rise due to a collapse or other adverse event if the determined instant magnitude does not exceed the first designated acceleration threshold magnitude for at least the first designated period of time;
- e) determines the first designated acceleration threshold magnitude from a plurality of previously determined instant magnitudes; and
- a communications unit that communicates an initiated event to a remote receiver.

In this aspect of the invention it is preferred:

- 20 the processing unit:
 - a) determines if the determined instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions exceeds a second designated acceleration threshold magnitude for at least a second designated period of time:
 - determines the second designated acceleration threshold magnitude from a plurality of previously determined instant magnitudes;
 - determines the magnitude of the instant angle of the subject being the magnitude of the angle between the cranio—caudal axis of the subject and the cranio—caudal axis of the subject when in an upright disposition from at least one of the determined instant acceleration of the subject in one or more determined directions;
 - d) determines if the determined instant angle of the monitor is greater or less than a designated angle magnitude threshold; and
 - e) initiates an event representative of an abnormally high acceleration of the subject followed by a laying down subject disposition indicative of a possible fall coupled with a subsequent absence of getting up from the laying down disposition indicative of a possible debilitating fall if:
 - the determined instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions exceeds the second designated acceleration threshold magnitude for at least a second designated period of time; and

- within a third designated period of time after the end of the second designated period of time the determined instant angle of the subject is greater than the designated angle magnitude threshold; and
- III. within the third designated period of time after the end second designated period of time the instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions does not exceed a third designated acceleration magnitude for at least a fourth designated period of time.

Preferably the accelerometer simultaneously determines the acceleration of the subject in three orthogonal directions.

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Preferably the portable monitor is mounted on an upright subject in an orientation so that one of the three orthogonal directions is in a vertical direction or within a designated angle of the vertical direction.

In another aspect the invention provides a method for detecting a person's inability to rise after a fall, 15 collapse or other adverse event using a triaxial accelerometer included in a personal wearable ambulatory monitoring device. The first part of the procedure involves the detection of an inability to rise caused by a fall event. The first step in the method is sampling an output from the triaxial accelerometer that is indicative of body acceleration and body angle. The next step is to determine whether a fall has taken place by comparing the magnitude of the acceleration vector to an acceleration magnitude 20 threshold for a period equal to a time duration threshold to determine the presence of an abnormal acceleration. If an abnormal acceleration is detected then the body angle is compared to a threshold value to identify a body state indicative of lying. A subsequent absence of movement is detected by comparing the magnitude of the acceleration vector to a second acceleration magnitude threshold. The second part of the procedure involves the detection of an inability to rise due to collapse or other 25 adverse event. The first step in the method is sampling an output from the triaxial accelerometer that is indicative of body acceleration and body angle. The next step is to identify an inability to rise by comparing the magnitude of the acceleration vector to an acceleration magnitude threshold for a period equal to a time duration threshold to determine the absence of a normal amount of movement.

In another aspect of the invention it provides a method for monitoring a person's movement to detect an inability to rise due to a fall through using a triaxial accelerometer included in a personal monitoring system that consists of a receiver unit and a personal monitoring device, which communicates with the

CLAIMS

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- 1. A monitoring apparatus for an ambulatory subject including:
 - a portable monitor mountable on the subject that includes an accelerometer that measures the instant acceleration of the subject in one or more determined directions;
 - a processing unit that:
 - determines at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time;
 - determines at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia;
 - determines if the subject's instant ambulatory performance indicia is below or above the at least one designated performance threshold;
 - d) initiates at least one event if the determined instant ambulatory performance indicia is above or below the determined at least one designated performance threshold; and
 - a communications unit that communicates an initiated event to a remote receiver.
- A monitoring apparatus in accordance with claim 1 wherein the at least one designated performance threshold is determined by the processing unit from a plurality of previously determined instant ambulatory performance indicia.
- 3. A monitoring apparatus in accordance with claim 1 wherein the at least one event is initiated only if the determined instant ambulatory performance indicia is below or above the determined at least one designated performance threshold for a designated period of time.
- 4. A monitoring apparatus in accordance with claim 3 wherein the designated first period of time is determined from a plurality of previously determined instant ambulatory performance indica.
 - . 5. A monitoring apparatus in accordance with claim 1 wherein the accelerometer simultaneously determines the acceleration of the subject in three orthogonal directions.
- 30 6. A monitoring apparatus in accordance with claim 5 wherein the portable monitor is configured to be mounted on an upright ambulatory such that one of the three orthogonal directions is in a vertical direction or within a designated angle of the vertical direction.
- A monitoring apparatus in accordance with claim 1 wherein an initiated event is communicated by
 the apparatus to the remote receiver by wireless communication.

Amended Sheet

- 8. A monitoring apparatus in accordance with claim 3 wherein:
 - a first instant ambulatory performance indicia representative of movement activity in the subject is determined from the instant magnitude of the sum of the instant acceleration of the subject in one or more determined directions;
 - a first acceleration threshold magnitude that is representative of a lack of normal expected subject movement is designated as a first designated performance threshold;
 - a first event representative of an absence of a normal amount of movement in the subject
 indicative of a possible inability to rise due to a collapse or other adverse event is initiated if the
 determined first instant ambulatory performance indicia is below the first designated acceleration
 threshold magnitude for a first designated period of time.
- 9. A monitoring apparatus in accordance with claim 8 wherein:
 - a second instant ambulatory performance indicia representative of the instant cranio-caudal
 angle of the subject relative to an upright disposition of the subject, is determined from at least
 one of the determined instant acceleration of the subject in one or more determined directions;
 - an angle magnitude that is representative of a cranio—caudal angle of the subject relative to an
 upright subject where the disposition of the subject is deemed to be no longer upright is
 designated as a second designated performance threshold;
 - a second acceleration threshold magnitude representative of an abnormally high subject movement is designated as a third designated performance threshold; and
 - a second event representative of an abnormal acceleration of the subject followed by a laying
 down subject disposition indicative of a possible fall coupled with a subsequent absence of
 getting up from the laying down disposition indicative of a possible debilitating fall is initiated if:
 - a) the determined first instant ambulatory performance indicia is above the second designated acceleration threshold for a second designated period of time; and
 - within a third designated period of time of the end of the second designated period of time the determined second instant ambulatory performance indicia is greater than the designated angle threshold; and then
 - the determined first instant ambulatory performance indicia is below the first designated acceleration threshold magnitude for a first designated period of time.
 - 10. A method of monitoring an ambulatory subject including:
 - a) mounting a portable monitor on the subject that includes an accelerometer to measure simultaneously the instant acceleration of the subject in at least three different directions at different instants in time;
 - using a processing unit in communication with the portable monitor to determine a plurality of instant ambulatory performance indicia based on the determined instant acceleration of the subject;

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- using the processing unit to determine at least one designated performance threshold corresponding to the each ambulatory performance indicia from at least one previously determined corresponding instant ambulatory performance indicia;
- d) using the processing unit to determine if the subject's instant ambulatory performance indicia is below or above the corresponding at least one designated performance threshold and initiating a corresponding event;
- e) using a communications unit to communicate an initiated event to a remote receiver.
- 11. A method of monitoring an ambulatory subject in accordance with claim 10 wherein the at least one designated performance threshold is determined from a plurality of previously determined instant performance indicia, and the designated performance threshold responsively and cooperatively adapts to statistical changes in previously determined instant performance indicia over time.
- 12. A method of monitoring an ambulatory subject in accordance with claim 10 wherein the event is initiated only if the determined instant ambulatory performance indicia is below or above the determined at least one designated performance threshold for a designated period of time.
 - 13. A method of monitoring an ambulatory subject including:

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- a) mounting a portable monitor on the subject that includes an accelerometer to measure the instant acceleration of the subject in one or more determined directions;
- using a processing unit in communication with the portable monitor to determine at least one instant ambulatory performance indicia of the subject from at least one determined instant acceleration of the subject in one or more instants of time;
- using the processing unit to determine at least one designated performance threshold from at least one previously determined instant ambulatory performance indicia;
- d) using the processing unit to determine if the subject's instant ambulatory performance indicia is below or above the at least one designated performance threshold and initiating a corresponding event;
- using the processing unit to initiate at least one event if the determined instant ambulatory performance indicia is above or below the determined at least one designated performance threshold; and
- using a communications unit to communicate an initiated event to a remote receiver.
- 14. A method of monitoring an ambulatory subject in accordance with claim 13 wherein the at least one
 35 designated performance threshold is determined by the processing unit from a plurality of previously determined instant performance indicia.

Amended Sheet

- 15. A method of monitoring an ambulatory subject in accordance with claim-13 wherein the designated performance threshold responsively and cooperatively adapts to statistical changes in previously determined instant performance indicia over time.
- 5 16. A monitoring apparatus for an ambulatory subject including:
 - a portable monitor mountable on the subject that includes an accelerometer that simultaneously measures the instant acceleration of the subject in at least three different directions;
 - a processing unit that:

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- f) is in communication with the portable monitor;
- g) determines the instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions;
- determines if the determined instant magnitude does not exceed a first designated acceleration threshold magnitude for a first designated period of time, where the first designated acceleration threshold magnitude is representative of a lack of normal expected subject movement;
- initiates an event representative of an absence of a normal amount of movement in the subject indicative of a possible inability to rise due to a collapse or other adverse event if the determined instant magnitude does not exceed the first designated acceleration threshold magnitude for at least the first designated period of time;
- determines the first designated acceleration threshold magnitude from a plurality of previously determined instant magnitudes; and
- a communications unit that communicates an initiated event to a remote receiver.
- 17. A monitoring apparatus in accordance with claim 16 wherein:
- 25 the processing unit:
 - a) determines if the determined instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions exceeds a second designated acceleration threshold magnitude for at least a second designated period of time;
 - determines the second designated acceleration threshold magnitude from a plurality of previously determined instant magnitudes,
 - determines the magnitude of the instant angle of the subject being the magnitude of the angle between the cranio—caudal axis of the subject and the cranio—caudal axis of the subject when in an upright disposition from at least one of the determined instant acceleration of the subject in one or more determined directions;
 - d) determines if the determined instant angle of the monitor is greater or less than a designated angle magnitude threshold; and
 - e) initiates an event representative of an abnormally high acceleration of the subject followed by a laying down subject disposition indicative of a possible fall coupled with a subsequent

absence of getting up from the laying down disposition indicative of a possible debilitating fall

- the determined instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions exceeds the second designated acceleration threshold magnitude for at least a second designated period of time; and
- II. within a third designated period of time after the end of the second designated period of time the determined instant angle of the subject is greater than the designated angle magnitude threshold; and
- III. within the third designated period of time after the end second designated period of time the instant magnitude of the sum of the instant acceleration of the subject in the at least three different directions does not exceed a third designated acceleration magnitude for at least a fourth designated period of time.
- 18. A monitoring apparatus in accordance with claim 16 wherein the accelerometer simultaneously determines the acceleration of the subject in three orthogonal directions.
- 19. A monitoring apparatus in accordance with claims 17 wherein the portable monitor is mounted on an upright subject in an orientation so that one of the three orthogonal directions is in a vertical direction or within a designated angle of the vertical direction.

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